EXHIBIT E

International Agency for Research on Cancer (IARC) - Summaries & Evaluations

N-NITROSODIETHYLAMINE

VOL.: 17 (1978) (p. 83)

CAS No.: 55-18-5
Chem. Abstr. Name: *N*-Ethyl-*N*-nitroso-ethanamine

5. Summary of Data Reported and Evaluation

5.1 Experimental data

N-Nitrosodiethylamine is carcinogenic in all animal species tested: mice, rats, Syrian golden, Chinese and European hamsters, guinea-pigs, rabbits, dogs, gerbils, pigs, monkeys, hedgehogs, various fish, frogs and birds. It induces benign and malignant tumours after its administration by various routes including ingestion, parenteral injection, inhalation and rectal instillation. The major target organs are the liver, respiratory and upper digestive tracts and kidney. It is carcinogenic following its administration prenatally and in single doses. In several studies, dose-response relationships were established.

N-Nitroso-*N*-ethyl-*N*-(2-hydroxyethyl)amine, a metabolite of *N*-nitrosodiethylamine, produced mainly liver tumours after its oral administration to rats.

5.2 Human data

No case reports or epidemiological studies were available to the Working Group. Available information on occurrence suggests that the general population may be exposed to low levels of *N*-nitrosodiethylamine; however, no exposed group suitable for an epidemiological investigation has yet been identified.

5.3 Evaluation

There is *sufficient evidence* of a carcinogenic effect of *N*-nitrosodiethylamine in many experimental animal species. Although no epidemiological data were available, *N*-nitrosodiethylamine should be regarded for practical purposes as if it were carcinogenic to humans.

Previous evaluation: Vol 1 (1972)

Subsequent evaluation: Suppl. 7 (p. 67: **Group 2A**)

For definition of terms, see Preamble Evaluation.

Synonyms

- DEN
- DENA
- *N,N*-Diethylnitrosamine
- Diethylnitrosamine
- Nitrosodiethylamine
- NDEA

See Also:
Toxicological Abbreviations